

510K Summary

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* We are **smith&nephew**

Submitted by: Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

Date of Summary: October 12, 2012

Contact Person and Address: Martin Ostmann
Regulatory Affairs Specialist
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Name of Device: Smith & Nephew, Inc. R3 Constrained Liner

Common Name: Acetabular Liner, Constrained

Device Classification Name and Reference: 21 CFR 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis

Device Class: Class II

Panel Code: Orthopaedics/87

Product Code: KWZ

OCT 16 2012

Device Description

The R3 Constrained Liners were previously cleared for market via premarket notification K111635. Subject of this premarket notification are minor modifications to the R3 Constrained Liner components, specifically the bipolar shell and inner poly liner.

The R3 Constrained Liners are available with inner diameters of 22 and 28mm and outer diameters from 52mm through 66/70mm. The devices are assembled from components that are made of ASTM F75 CoCr, ASTM F90 CoCr, ASTM F1472 Ti-6Al-4V, and ASTM F648 UHMWPE.

Technological Characteristics

Mechanical testing has been conducted to address the attachment loads (push-in, push-out, shuck-out) of the R3 Constrained Liner components as well as to address simulated intraoperative dislocation. A review of the results indicates that the R3 Constrained Liners are equivalent to existing, legally marketed predicate devices with regards to mechanical performance and that there are no new issues related to the safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

Intended Use

The R3 Constrained Liner Acetabular System is a cemented or uncemented prosthesis intended to replace a hip joint. The Constrained Liner is intended for primary or revision patients at high risk for hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. The R3 Constrained Liner is intended for single use only.

Substantial Equivalence Information

The subject devices are identical in function, intended use, indications for use, and material composition, and very similar in overall design to the R3 Constrained Liners cleared via premarket notification K111635.

Table 1: Substantially equivalent predicates to the R3 Constrained Liner

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	R3 Constrained Liner	K111635	9/9/2011
Smith & Nephew, Inc.	Reflection Constrained Liners	K021803 K033442	12/19/2002 11/26/2003
Depuy, A J&J Company	S-Rom Constrained Liner	P960054	6/19/1997

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the modified R3 Constrained Liners. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to above predicate constrained hip systems.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith and Nephew, Incorporated
% Mr. Martin Ostmann
Regulatory Affairs Specialist
1450 East Brooks Road
Memphis, Tennessee 38116

OCT 16 2012

Re: K122139

Trade/Device Name: R3 Constrained Liner

Regulation Number: 21 CFR 888.3310

Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Regulatory Class: Class II

Product Code: KWZ

Dated: July 17, 2012

Received: July 19, 2012

Dear Mr. Ostmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

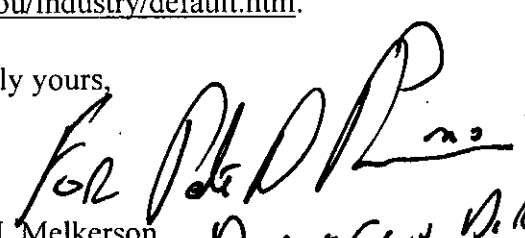
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K122139 (pg 1/1)

Device Name: R3 Constrained Liner

Indications for Use:

The R3 Constrained Liner Acetabular System is a cemented or uncemented prosthesis intended to replace a hip joint. The Constrained Liner is intended for primary or revision patients at high risk for hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. The R3 Constrained Liner is intended for single use only.

Prescription Use X
(Part 21 CFR 801.109)

AND/OR

Over-the-Counter Use
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for K. Asanah
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122139

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